

Appl. No. 10/720,932  
Amdt. Dated 21-Feb-05  
Reply to Office Action of September 21, 2004  
Attorney Docket No. : 6051-009

### Remarks/Arguments

In the Examiner's Non-Final Office Action dated September 21, 2004, the Examiner took the following action:

1. Rejected Claims 7-11 under 35 U.S.C. §112, second paragraph, as being indefinite; and
2. Rejected Claims 1-11 under 35 U.S.C. §102(e) as being anticipated by Garrison et al. U.S. Patent No. 6,425,916.

### Background of the Law

In order to establish proper anticipation under 35 U.S.C. §102, each and every element of the claimed invention must be disclosed in a single prior art reference. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). The claimed elements either be inherent or disclosed expressly in the single prior art reference *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988) and must be arranged as in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989). The absence from the reference of any claimed element necessarily negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 220 USPQ 81 (Fed. Cir. 1986).

### Amended Claim 7 Traverses the Rejection under 35 U.S.C. §112, second paragraph

Applicant has amended Claim 7 in conformity with the specification originally filed. The Examiner is correct in noting that the second section, corresponding to the dilatation balloon, resides proximal the first section, corresponding to the valvular prosthesis. Applicant's recitation in Claim 7 of the inverse positioning was erroneous and was not submitted with any intent to deceive. Applicant gratefully acknowledges the Examiner's recognition of this error, and submits that Amended Claim 7 traverses the §112, second paragraph rejection.

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§102(e) Rejection: Garrison, et al. Fails to Disclose the Correspondingly Claimed Elements

Applicants respectfully submit that the Garrison, et al. reference fails to teach each and every element of the invention as claimed in Claims 1-11. Specifically, Garrison, et al fail to teach, either expressly or by implication, a catheter in which a first section bearing the valvular prosthesis is distal the second section bearing the dilatation balloon, such that during the claimed delivery method, the first section bearing the valvular prosthesis is advanced distal the anatomic valve to permit dilatation of the anatomic valve, then after such dilatation, the catheter is proximally withdrawn to position the valvular prosthesis on the first section within the situs of the anatomic valve for deployment.

Claim 1 has been amended to clarify that when the second section, i.e., the balloon section is positioned within the situs of the anatomic valve, the first section, i.e., that having the valvular prosthesis, is positioned distal the anatomic valve. This position would correspond to that illustrated in Figures 20A-20C of the present invention. This positioning makes clearer that the distal first section bearing the valvular prosthesis paced distal the valve so that the valve may be dilated using the balloon on the proximal second section, then the catheter moved proximally so that the valvular prosthesis on the first section may be engaged with the anatomic valve situs and then deployed.

This arrangement permits the physician to advance the delivery catheter a single time, then dilates the anatomic valve, then employing only proximally oriented motion, deploy the valvular prosthesis and withdraw the catheter.

The claimed method is in sharp contrast to the device and method describe in Garrison, et al, which employs a two-part catheter and two-part device. See, e.g., Col. 6, lines 45-56, describing a first catheter 62 carrying the valve displacer 8 (stent) and a second catheter 64 which carries the valve 6. The delivery catheter arrangement of the Garrison, et al. reference is, in fact, the inverse of that claimed in the presently pending claims. Specifically, the valvular prosthesis 6 of Garrison, et al is positioned proximal to the distal dilatation balloon 50. This arrangement requires the physician to first dilates

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the valve and place a valve displacer 8 (stent), then move the catheter distally to place the valve 6, then withdraw the entire assembly. Thus, the method described in Garrison, et al. does not read on the method as claimed in the pending claims.

With particular regard to Claims 4 and 9, there is a complete absence of disclosure in Garrison, et al that the valvular prosthesis includes anchoring flanges which project substantially radially outwardly from the valvular prosthesis at a distal end of the valvular prosthesis, and in which the method includes withdrawing the sheath to deploy the anchoring flanges, and engaging the anchoring flanges to the distal end of the anatomic valve, thereby positioning the valvular prosthesis within the anatomic valve. Rather, in the Garrison, et al. reference, the valvular prosthesis is delivered within the lumen of the valve displacer 8, which has already been placed in the anatomical valve situs. In this arrangement, the anchoring flanges as present claimed are neither present in Garrison nor are even functionally feasible.

With respect to Claims 5 and 10, there is no suggestion in the Garrison, et al reference that the delivery profile of the device of that reference would be of a 12 French or smaller.

Finally, with respect to Claims 6-11, these claims require the presence of an annular plug coupled to the guidewire shaft in the catheter device which is absent from the Garrison, et al. reference.

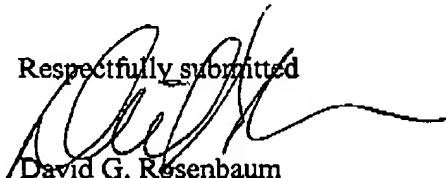
Accordingly, Applicants respectfully submit that Claims 1-11 traverse each of the rejections of record and request that favorable reconsideration of the rejections be made and that pending Claims 1-11 be allowed to pass to issue.

This Amendment Letter is being concurrently filed with a Notice of Change of Address, a Notice of Change of Entity Status, and an Amendment Transmittal which includes a fee calculation sheet and a Request for Extension of Time. Other than the extension fee identified in the Amendment Transmittal, no other fees are believed necessitated by this Amendment. Should, however, any such fees be required, the Director is hereby authorized to deduct them from the Deposit Account of Rosenbaum & Associates, P.C. No. 18-2000, of which the undersigned is an authorized signatory.

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Should there be any further outstanding issues which the Examiner believes may be susceptible of resolution by a telephonic interview, the Examiner is encouraged to telephone the undersigned attorney-of-record at the below-identified telephone number regarding such matters.

Respectfully submitted



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